

### **SUPPLEMENTAL EXAMINER'S AMENDMENT**

Applicant's filing of the RCE (vacating the previous Notice of Allowance) to submit the IDS's of 1/17/08 and 3/11/08 are acknowledged. The art has been thoroughly reviewed and does not change the previous disposition of the allowability of claims as amended below. A copy of the signed/initialed 1449 is sent herewith.

The present Examiner's Amendment mirrors that of the previous Examiner's Amendment mailed 10/28/07, based on same outstanding claims, filed 6/19/07.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was approved by Michael Willis, Applicant's Representative, during a telephone conversation held on 8/30/07.

[NOTE: Single change in supplemental Examiner's Amendment appears in bold below].

#### **IN THE CLAIMS**

In claims 1 and 18, the phrase “, prodrugs, tautomers, and solvates,” has been deleted.

In claims 21-23, the phrase “, 16, 17, 18, 29, and 20” has been deleted and the phrase --or 18-- inserted.

**In claims 24, line 1, the phrase “any one of claims 1, 16, and 17” has been deleted and the phrase --claim 1-- inserted.**

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In claims 25-26, the phrase “any one of claim 18-20” has been deleted and the phrase --claim 18-- inserted.

In claim 26, the phrase “, 16, 17, 18, 29, and 20” has been deleted and the phrase --or 18, wherein the form of cancer is selected from the group consisting of prostate, ovarian, breast, melanoma, lung, leukemia, pancreatic, colon, cervical and hepatic--.

In claim 30, the phrase “cancer is selected from prostate cancer, breast cancer, hepatocellular carcinoma, melanoma, colorectal cancer, renal cancer, ovarian cancer, lung cancer, leukemia, epithelial cancer, pancreatic cancer, and tumors that overexpress the Her2/neu oncogene” has been deleted and the phrase --the form of cancer is selected from melanoma, colon, ovarian, lung, leukemia, and pancreatic-- inserted.

Claims 16-17, 19-20, 29, and 32-33 have been cancelled without prejudice.

### ***Reasons for Allowance***

The following is an examiner’s statement of reasons for allowance:

The prior art of record does not reasonably teach or suggest the presently claimed products and methods of making and treating certain forms of cancer therewith. Specification Examples 6-8 provide appropriate cell line data regarding the enablement of the products of the invention to be used in a method of treating the now amended forms of cancer, in claims 26 and 30.

Scheuer et al. (US 6,274,551 and 6,011,010) is deemed the closest prior art of record. Scheuer et al. teach 5-methylhexanoic KF, while the present invention is drawn to 4-methylhexanoic KF. Although appearing slight, as Applicant describes, the modification from 5-

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to 4-methylhexanoic KF evidenced unexpected results, and for these reasons, cannot be deemed merely an obvious modification. As described on present specification pages 6-7:

#### **DETAILED DESCRIPTION OF THE INVENTION**

We have identified analogues of Kahalalide F that show significant improvement in activity with respect to Kahalalide F. As shown in the comparative examples, the 4-methylhexanoic KF has unexpectedly shown significant improved efficacy in *in vivo* cancer models. This is the more surprising in view of the small structural difference between 4-methylhexanoic KF and 5-methylhexanoic KF.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### ***Conclusion***

Claims 1, 18-28 and 30-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MA, 3/30/2008

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